



BIOVERSYS ANNOUNCES FIRST PATIENT DOSED IN PHASE 2 CLINICAL TRIAL WITH BV100

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BioVersys AG announces first patient dosed in Phase 2 clinical trial with BV100

BioVersys AG, a privately-held clinical stage, multi-asset Swiss pharmaceutical company focusing on research and development of small molecules for multidrug-resistant bacterial infections with applications in antimicrobial resistance (AMR) and targeted microbiome modulation, announced today, that the first patient has been dosed in a multicenter Phase 2 clinical trial with BV100.

BV100 is a novel formulation of rifabutin suitable for intravenous administration. BV100 is based on the newly identified mode of action for active uptake of rifabutin into *Acinetobacter baumannii-calcoaceticus complex*, thus rendering the bacteria hypersensitive to rifabutin. BV100 is being developed for hospital infections caused by *Acinetobacter baumannii*, including carbapenem resistant strains (CRAB), which ranks on the highest priority of the WHO and CDC list of priority pathogens. There is a serious lack of effective and safe treatment options for CRAB infections and mortality rates in the hospital can be as high as 50%.

- BV100 is being studied in a multicenter, open label, randomized, active controlled, Phase 2 study to evaluate the pharmacokinetics, efficacy, and safety of BV100 in adult patients with ventilator associated bacterial pneumonia (VABP) suspected or confirmed to be due to CRAB.
- BV100 was already shown in Phase 1 clinical trials to be generally safe and well tolerated with favorable pharmacokinetic profile in single and multiple ascending dose studies, as well as in a study in patients with varying degrees of renal impairment.

Dr. Glenn E. Dale, Chief Development Officer of BioVersys: “Following the promising safety profile shown in Phase 1, we are delighted to be testing BV100 for the first time in patients in Phase 2. The study will look at the efficacy, safety, tolerability and in particular the pharmacokinetics of BV100, in VABP patients with suspected or confirmed CRAB infection.”

Prof. Apostolos Armaganidis, MD, Attikon University Hospital, Athens: “As a long time clinician of pulmonary and intensive care medicine in Athens, I have been witness to high levels of *Acinetobacter baumannii* drug-resistance. During the COVID-19 pandemic the situation worsened and even Colistin, often the only working and last resort antibiotic, faced as much as 60-70% resistance. Therefore, I am very encouraged to see BV100 being tested in VABP patients for the first time, and the promise it brings of a new lifesaving therapeutic treatment option for CRAB patients.”



Dr. Marc Gitzinger, Chief Executive Officer and founder of BioVersys: “Moving BV100 into Phase 2 is an important next step in developing our pipeline of pathogen-focused products against the highest priority bacterial infections, targeting the most important health threats. Our two lead assets are now in Phase 2 clinical trials and we look forward to delivering these much needed drug candidates to patients in need and ultimately creating shareholder value.”

About BV100

BV100 is a novel formulation of rifabutin suitable for intravenous administration, with a recently discovered novel mode of action showing an active uptake of rifabutin into the Gram-negative bacterial species, *Acinetobacter baumannii*. The candidate allows to target RNA-polymerase in Gram-negative bacteria for the first time with a human-suitable dose. BV100 is being developed for the treatment of infections caused by *Acinetobacter baumannii calcoaceticus complex* (ABC), including Carbapenem-Resistant ABC (CRAB) in critically important indications of ventilator associated bacterial pneumonia (VABP), hospital-acquired bacterial pneumonia (HABP) and bloodstream infections (BSI). BV100 was granted QIDP Designation by the U.S. FDA in May 2019 for use in the treatment of VABP, HABP and BSI, making BV100 eligible for priority FDA review, Fast Track designation, and a five-year extension of market exclusivity upon approval of the first QIDP indication.

About *Acinetobacter baumannii*

Acinetobacter baumannii calcoaceticus complex (ABC) are Gram-negative bacteria found in the environment (e.g., in soil and water) and an opportunistic pathogen in humans, typically infecting critically ill and immunocompromised patients, that can result in severe pneumonia and bloodstream infections in addition to affecting other parts of the body. ABC is considered a significant worldwide threat in the healthcare setting given its ability to survive for prolonged periods on surfaces, combined with its ability to develop or acquire resistance to standard of care antibiotics, e.g. carbapenems. Carbapenem-resistance as well as multidrug-resistance (MDR) rates for ABC are among the highest recorded for any bacteria in current times (*The Lancet* 2022; 399: 629–55). Incidence and resistance rates for ABC are trending upwards and COVID-19 has exacerbated this significantly. BioVersys forecasts the annual number of carbapenem-resistant *A. baumannii* infections in the hospital to have surpassed one million globally and due to the limited treatment options, such infections come with high (50%) mortality rates.

About BioVersys

BioVersys AG is a privately owned, clinical stage Swiss pharmaceutical company focusing on research and development of small molecules acting on novel bacterial targets with applications in antimicrobial resistance (AMR) and targeted microbiome modulation. With the company's award-winning TRIC technology, candidates can overcome resistance mechanisms, block virulence production and directly affect the pathogenesis of harmful bacteria towards the identification of new treatment options in the antimicrobial and microbiome fields. This enables BioVersys to address the high unmet medical need for new treatments against life-threatening resistant bacterial infections and bacteria-exacerbated chronic inflammatory microbiome disorders. The company's most advanced research and development programs address nosocomial infections of *Acinetobacter baumannii* (BV100, Phase 2), and tuberculosis (BVL-GSK098, Phase 2a, in collaboration with GlaxoSmithKline (GSK) and a consortium of the University of Lille). BioVersys is located in the Tech Park Basel in the biotech hub of Basel.

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